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Experimental Study and Preliminary Clinical Application of Mini-invasive Percutaneous Internal Screw Fixation for Scaphoid Fracture under the Guidance of a 3D-printed Guide Plate*

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Summary: This study explored the feasibility of employing computer-aided design (CAD) and 3 dimensional (3D)-printed personalized guide plate for the mini-invasive percutaneous internal screw fixation of fractured scaphoid. The study consisted of two parts: (1) experimentation on upper limbs from corpses and (2) preliminary clinical application. Corpse experiments involved upper limbs of 6 adult corpses. The specimens of upper limbs were subjected to plain CT scan. Then the CT data were input into computer to conduct 3D reconstruction of wrist region. The direction and depth of the guide wire and screw were designed on the basis of the principle that screw should lie at the center of scaphoid and the long axis of the screw should be aligned with that of the scaphoid. The carpal bone model and the guide plate were designed and 3D-printed. By using the guide plates, the guide wire was placed and the cannulated compression screw was inserted. The wrist region was examined by X-ray and CT to observe the location of the screw in the scaphoid. The scaphoid was longitudinally excised to grossly observe the location and evaluate the result of screw insertion. For clinical application, the guide plate was employed in 4 patients with fresh scaphoid fracture using the aforementioned operative technique. Our results showed that, in the 6 corpse limbs, the guide plate well fitted the skin surface and the guide wire and screw were accurately put in place in one session. X-ray examination and gross observation confirmed that the screw was satisfactorily positioned and the result met the requirements of the preoperative design. For 4 patients, the guide wire and screw were all precisely inserted into place in one session. The operation time and X-ray exposure times were apparently reduced. The imaging examination exhibited satisfactory results and the hand functioned well. It was concluded that the operative guide plate used for the mini-invasive percutaneous internal screw fixation of fractured scaphoid not only can assist in accurate placement of screw but also shorten operation time and reduce insertion and X-ray exposure times, thereby reducing the radiation injury and damage to the substance and the blood circulation of carpal bone. Its use can also improve the learning curve of surgeons.
Key words: fracture of scaphoid bone; 3-dimensional printed guide place; mini-invasive operation; screw insertion

The unique anatomy and biomechanical properties of the scaphoid make the bone most susceptible to fracture among carpal bones. The blood supply of scaphoid renders its post-fracture healing very difficult and the necrosis rate of proximal bone fragments and non-union rate of the fracture are high[1]. Therefore, the scaphoid fracture and related issues have been a subject of active studies in hand surgery.

For non-displaced fresh scaphoid fracture, the traditional management is external fixation with plaster cast. Nonetheless, the plaster cast is non-air-permeable, subject to dirt, odorous and itch-causing. Moreover, long-term fixation with plaster cast can lead to muscular atrophy, joint stiffness and disuse, etc. Open reduction and internal fixation can achieve anatomical reduction and allow for early exercise but it entails incision of joint capsule, extensive isolation of surrounding tissues, thus causing extensive trauma and interfering with blood circulation[1–4]. The percutaneous internal screw fixation can well resolve the aforementioned problems but it also has the following shortcomings: (1) It heavily depends on the skill and experience of the surgeons. The screw should be positioned in the right middle of the scaphoid and be aligned with the

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bone[5–7], which poses great challenge to inexperienced surgeons. (2) Repeated adjustment of guide wire is needed, which protracts the operation time, possibly damages the bony intactness and blood circulation, and increases the possibility of complications. (3) Multiple radiological checks increase the radioactive exposure of both doctors and the patients involved. (4) The percutaneous fixation might have to be converted to open surgery, which inflicts more pain on the patient[8, 9]. To address the above-mentioned problems, we designed a 3 dimensional (3D) printed guide plate for the percutaneous internal screw fixation of fractured scaphoid. To confirm the feasibility of using the guide plate, we conducted experimental study in 6 corpse specimens and performed the operation using the guide plate in 4 patients.

1 MATERIALS AND METHODS

1.1 Experimental Study

1.1.1 The Guide Plate The guide plate had three components (fig. 1): a channel, a fixator and a locker. The angle and locating points of the channel were so designed that it helped Kirschner wire to eventually lie right in the middle of the scaphoid and was aligned with the long axis of the bone. The fixator was designed according to the skin texture and bony landmarks, to well fit the skin of wrist region. (3) The locker served to anchor the fixator on the palmar and dorsal sides and was easy to disassemble and assemble. The inset B of figure 1 shows the 3D model of wrist specimens.

1.1.2 Methods Six specimens of structurally-intact adult upper limbs were kindly provided by the Department of Anatomy of Southern Medical

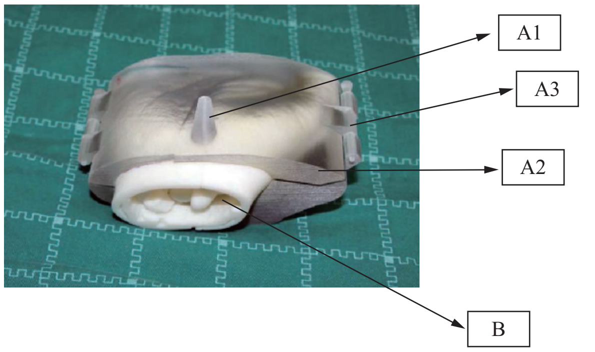

Fig. 1 3D-printed guide plate and the wrist model of limb specimen
A1: channel of the guide wire; A2: wrist fixator; A3: locker; B: wrist model of lime specimen

University, Guangzhou, China. They were numbered and subjected to plain CT scan (section thickness: 0.625 mm), with palmar side facing up, on a 64-row spiral computed tomography (MSCT) system. The data were stored in the format of DICOM (version 3.0). Mimics14.0 software package was employed for 3D reconstruction. On the basis of the principle that screw should lie at the center of scaphoid and the long axis of the screw should be aligned with that of scaphoid, with palmar side taken as approaching point, we designed the entry point, the direction of screw advancement, depths of screw at various tissue layers, with the optimal length of the screw in the scaphoid determined. The guide plate was designed by using transverse, distal palmar and thenar creases and bony prominences as location marks. And effect pictures were drawn to show a Kirschner wire going through the guide plate and into the scaphoid under guidance of the plate placed on the wrist (fig. 2). The designed guide plate

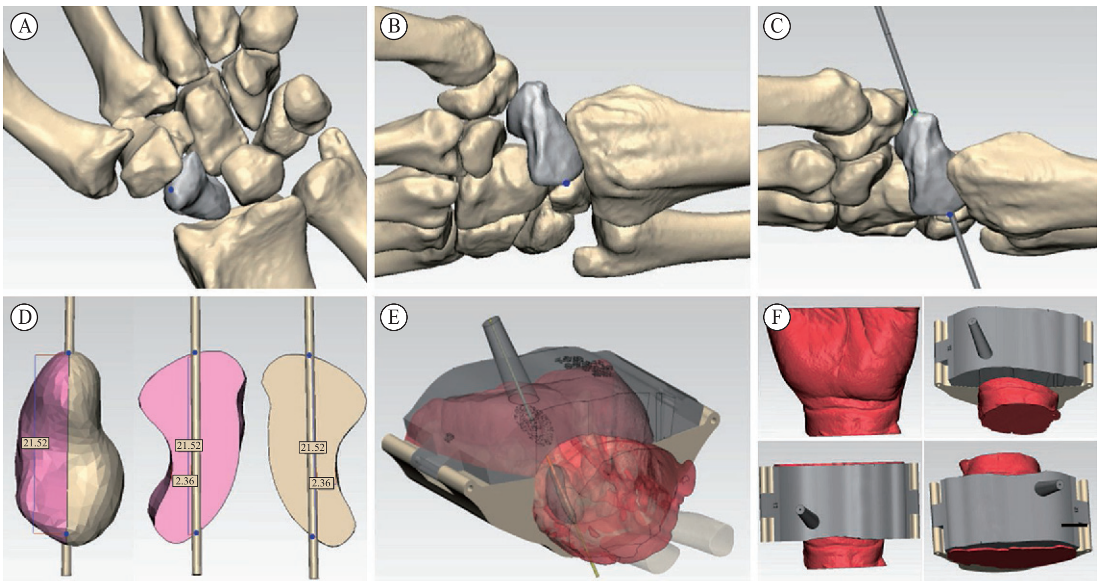

Fig. 2 Guide wire, screw, screw channel and the drawing of the guide plate
A: entry point; B: exit point; C: Kirschnner wire going through the scaphoid; D: measurement of the length of the screw in the scaphoid; E: installation of the guide plate and introduction of Krischner wire; F: The effect picture of CAD-determined skin location marks and the guide plate installed on the wrist

was digitally exported to a 3D printer[10, 11]. MED610 biocompatible resin was used for the printing of the guide plate and a photo-sensitive resin for the printing of scaphoid mode[12, 13]. The guide plate was mounted on the scaphoid model and a 1.0-mm Kirshner wire was inserted. Then the fit of the plate, the rationality and accuracy of the plate channel and entry and exit points were preliminarily evaluated against the design criteria (fig. 3). Then the guide plate was fixed on the wrist of a limb specimen. Care was exercised to make sure that the guide plate was accurately positioned and fitted snugly around the wrist by meticulously identifying skin creases and bony prominences. According to the insertion depth and optimal screw length, as previously determined by computer-aided design (CAD), a 1.0-mm Kirschner wire was introduced into the scaphoid of the limb specimen. After radiological check, a Herbert cannulated compression screw of proper length was placed (fig. 4). The location of the screw was observed by plain X-ray film and CT. Afterwards, the entire scaphoid was surgically taken out and longitudinally incised for gross examination of the trajectory and

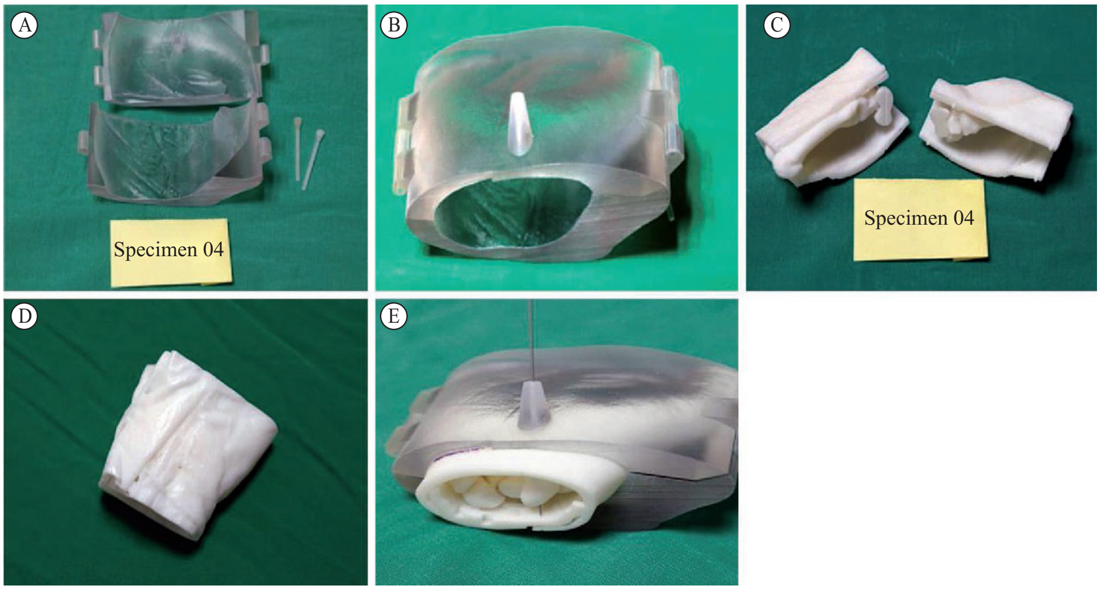

Fig. 3 Making and printing of the guide plate and wrist model

A: before installation of the guide plate; B: installation of guide plate; C: before assembling of wrist model; D: After assembling of wrist model, the guide wire was introduced under the guidance of the plate; E: introduction of the guide wire into fracture model

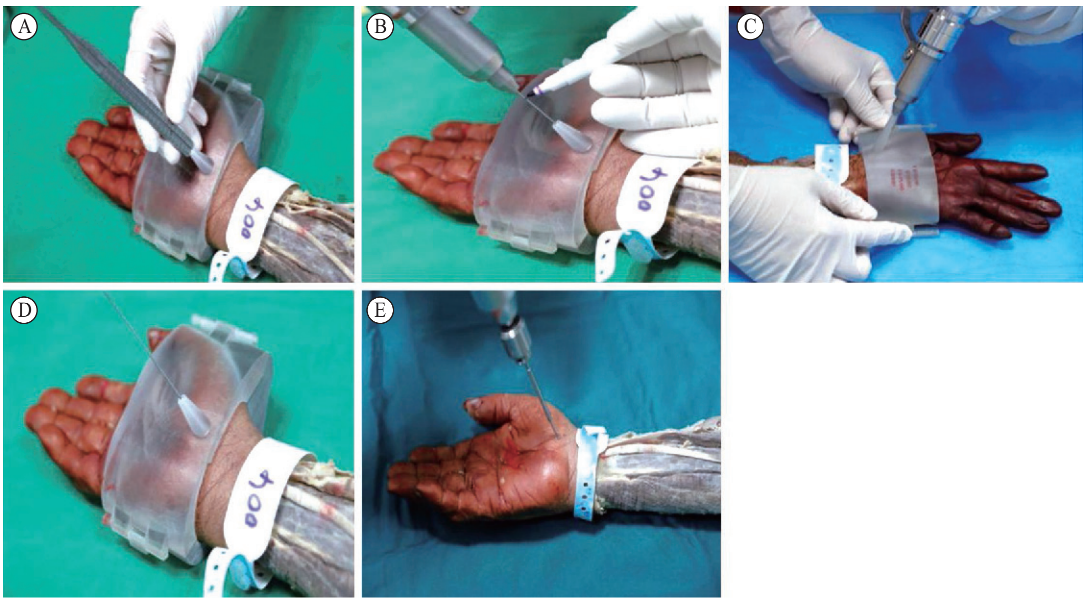

Fig. 4 Introduction of the guide wire and the screw

A: measuring the length of guide wire; B: marking the length of the guide wire; C: introduction of the guide wire; D: the guide wire introduced into the scaphoid; E: insertion of the screw under guidance of the guide wire position of the screw (fig. 5).

1.1.3 Observational Measures Screw insertion time: Screw insertion time refers to the time from the installation of guide plate to the radiological confirmation of satisfactory screw placement, involving plate installation, length measurement, introduction of guide wire and screw and two radiological checks; X-ray imaging: Upon insertion of the guide wire and screw, anteroposterior and lateral films of the wrist were taken to observe the screw in the scaphoid. The result was rated as satisfactory if the screw lay in the middle of the scaphoid and its axis was aligned with the long axis of the bone, with the screw tail below the articular surface. CT: After X-ray films showed satisfactory insertion of the screw, the scaphoid was subjected to plain CT and 3D reconstruction to review the screw in the scaphoid. The same criteria for satisfactory insertion used in X-ray checks were applied. Post-insertion CT data of the specimens were compared with those of the CAD and the distance deviation of the entry point and angle deviation of the screw trajectory were calculated (fig. 6). Gross examination: The cross-section of the scaphoid was grossly observed and assessed with unaided eyes. The satisfactory screw insertion was judged against the aforementioned criteria for X-ray checks.

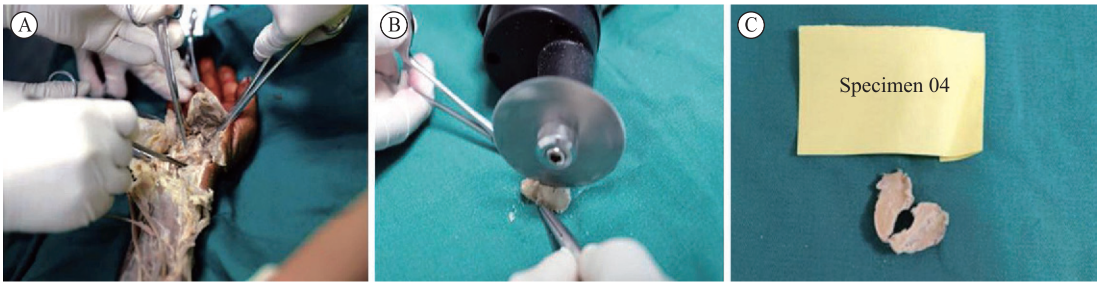

Fig. 5 Gross observation of the position of screw trajectory
A: incision of a specimen; B: a scaphoid cut open along its longitudinal axis; C: position of the screw trajectory in the scaphoid

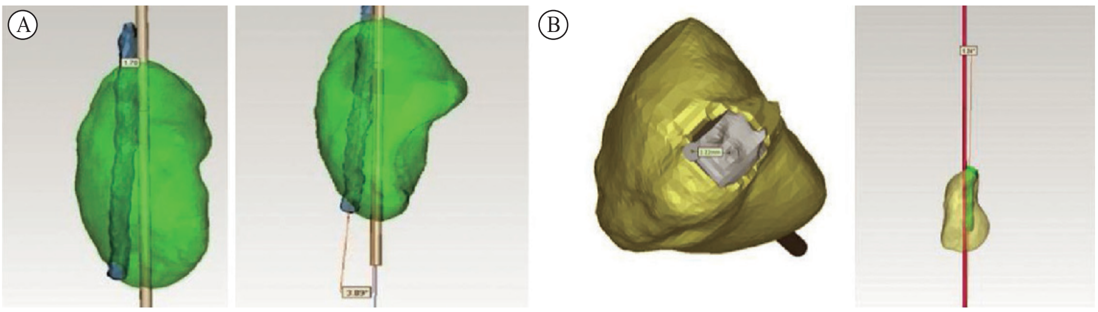

Fig. 6 The screw positioned against the CAD-designed position
A: coronal plane; B:cross section

1.2 Clinical Application

1.2.1 General Data Four males, aged 30–53 years, sustained from fresh scaphoid fracture after fall. The fracture was at the middle of the scaphoid, in the right wrist in 3 cases and in the left wrist in one case. Before the treatment, informed consents were obtained from all participants. The study was approved by the Ethics Committee of Peking University Shenzhen Hospital. The patients received the anteroposterior and lateral X-ray examination and were subjected to plain CT scan for 3D reconstruction to assess the fracture. The examinations revealed no apparent dislocation and the patients were all indicated for the internal fixation under the guidance of the 3D-printed guide plate. The identical methods were used for preoperative fabrication of the guide plate.

1.2.2 Operative Technique In 4 patients, palmar approach was used. The patient assumed supine position and the brachial plexus anesthesia was employed, with pneumatic tourniquet routinely placed on the upper arm. The affected arm rested horizontally on the operation table, with the forearm rotating externally and the palmar side facing up. The guide plate was installed, and the recording of operation time began. The skin creases or folds and bony prominences were carefully identified and then the guide plate was accurately and fittingly installed on the wrist region. A 1.0-mm Kirschner wire was inserted to a pre-determined depth and if X-ray check showed that the wire was satisfactorily positioned, a core drill was used to drill the scaphoid. Afterwards, a Herbert cannulated compression screw of proper length was placed. If a radiological re-check

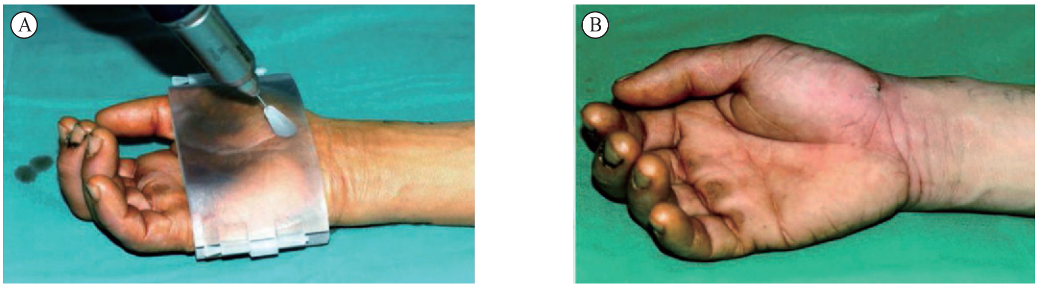

Fig. 7 Procedures in clinical cases
A: installation of the guide plate and introduction of guide wire; B: A stitch was placed after the operation was finished

showed that the screw was satisfactorily positioned, the time recording was terminated and the guide wire was removed. If the wound of screw trajectory was big, a stitch was placed (fig. 7). The times of radiological checks were also recorded.

1.2.3 Postoperative Management The wrist region should be kept dry for 2 weeks until the skin wound healed. Strenuous exercise or activities should be avoided, such as boxing, chinning, push-ups, weight-lifting, among others. The patient could exercise the wrist and other hand joints and performed daily activities, including eating, putting on clothes and writing, etc. During the time between these activities, patients could wear removable fixed wrist brace for protection. The wrist was radiologically checked on daily basis until the bone fracture healed.

2 RESULTS

The total screw insertion time in the 6 upper limb specimens was 20.5, 20.1, 20.8, 20.7, 20.0, and 19.9 min, with 20.3 min on average.

X-ray, CT and gross observation all showed that the guide wire and screw were located in the middle of the scaphoid and the screw axis was roughly aligned with the long axis of the scaphoid. The screw was of proper length and was fully embedded in the scaphoid and did not penetrate the proximal bone cortex (fig. 8). The distance deviation of the entry point and angle deviation of the screw trajectory were, on average, 1.86 mm and 2.67° respectively (table 1).

The total operation time in the 4 cases was 19.8 min on average and they received two intraoperative radiological checks (table 2).

Intraoperatively, X-ray examination revealed that the guide wire was on the middle axis of the scaphoid and the screw was satisfactorily positioned and was of proper length (fig. 9). Postoperative re-examination exhibited that the fracture healed as expected.

3 DISCUSSION

3.1 Experimental steps and Results

According to literature[14], CT scan at a slice thickness of <1 mm can generate clear 3D images. This study used a slice thickness of 0.625 mm and the data obtained could be used for accurate 3D image generation of carpal bones and satisfied the requirements for CAD, 3D printing of the guide plate and imaging observation. The total time for CAD and printing was 12.5 h and the cost was approximately RMB 3000 yuan (about 420 US dollars). With the widespread application of 3D technologies and equipment, the price is expected to be further reduced and the time taken will be shorter. The experimental test on limb specimens and clinical application in 4 cases showed the screw insertion under the guide plate could shorten operative time and reduce times of radiological check. The computerized measurement could provide rational operative plan and ensure accuracy. X-ray examination, CT scan, 3D reconstruction and gross observation all showed the guide wire and screw could be precisely introduced in one session under the 3D-printed guide plate. The 3D wrist model was close to real bones, can be marked and used for training and experimentation, which

Table 1 Distance deviation of entry point and angle deviation of screw trajectory

Items	Specimen No.						Mean
	01	03	04	08	10	12	
Distance deviation (mm)	1.50	1.93	2.00	1.70	1.82	2.22	1.86
Angle deviation (°)	3.10	3.50	1.50	3.89	2.80	1.24	2.67

Table 2 Operative time and times of radiological check

Case	Total operative time (min)	Radiological checks (times)
1	18.5	2
2	21.1	2
3	19.3	2
4	20.2	2
Mean	19.8	2

Fig. 8 X-ray films, CT images and gross appearance of some cross-sections of the scaphoid after screw insertion

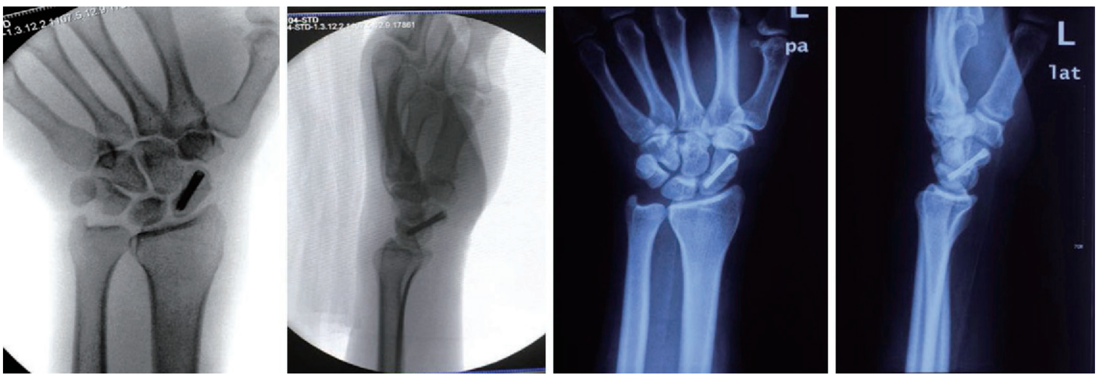

Fig. 9 Intra- and post-operative X-ray films of clinical cases

help surgeons hone operative skills. There were some deviations between design values and real results but the discrepancies were within the acceptable ranges. The possible causes for the discrepancies might be ascribed to the facts that (1) the skin of the limb specimens was dry and non-elastic, which led to a less perfect fit between the plate and wrist region; (2) screw advancement might push the soft tissues; (3) installation of the plate might cause positional change of the scaphoid; (4) with a small bone like the scaphoid, these slight errors might add up to great displacement of the bone.

3.2 Indications for the Use of the Guide Plate and Some Suggestions

The internal fixation under the guide plate is suitable for fresh and non-displaced scaphoid fracture or the scaphoid fracture with displacement that can be anatomically reduced. Old or non-healing scaphoid fracture, fresh scaphoid fracture but with displacement are not indicated for use of the guide plate. Attention also should be paid to the swelling at wrist region. Whenever possible, after injury, CT for plate design and making should be conducted before swelling develops. The best fit around the wrist region can be achieved after swelling vanishes. If apparent swelling develops, the operation is not recommended since swelling might pose surgery-related danger and a wrong-sized plate might be designed or made. It is desirable to begin designing the plate after swelling disappears. Care should be taken during plate installation to avoid crushing or pinching the wrist. The guide wire should be protected or guarded in the process of plate dismantling and screw insertion, since the screw and wire might come out during the processes.

3.3 The Advantages of the Plate-guided Internal Fixation of the Scaphoid

Percutaneous internal fixation with screw asks for accurate positioning of the screw and demands experience and skills on the part of surgeons. With the guide plate, young or inexperienced doctors can also perform the operation, thus allowing for a substantially improved learning curve. Traditional fixation requires multiple and long-time X-ray checks, while the plate-guided fixation needs only two radiological checks, which helps reduce radioactive exposure of both doctors and patients. The fixation with the aid of the guide plate takes less time, which helps to protect the wrist bones and adjacent soft tissues, minimizes the damage to blood circulation. Fixation of the wrist with the plate can avoid the influence of body movement on the screw insertion. As long as the plate is correctly installed, the wrist will in a position which is consistent with the position when the wrist is CT-scanned. Therefore, the plate-guided fixation has conspicuous advantages over the traditional techniques. Since we only tested it in 4 cases, more work needs to be done to accumulate experience and find problems that have to be addressed.

Conflict of Interest Statement

The authors declare that there is no conflict of interest with any financial organization or corporation or individual that can inappropriately influence this work.

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